Attorney Docket No.: 10142 - 04001 (03-318)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

| In re Application of: | |
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| Girard et al. | |
| Serial No.: 10/752,257 | Group Art Unit: 3767 |
| Filed: January 6, 2004 | Examiner: Phillip A. Gray |
| For: INJECTION ACCESS PORT WITH) CHAMFERED TOP HAT SEPTUM) DESIGN | Board of Patent Appeals and Interferences |

Mail Stop: Appeal Brief - Patents Commissioner for Patents P.O. Box 1450 Arlington, VA 22313-1450

APPEAL BRIEF UNDER 37 C.F.R. § 41.37

In support of the Notice of Appeal filed on July 31, 2008, in response to the Notification of Non-Compliant Appeal Brief mailed on September 8, 2008, and pursuant to 37 C.F.R. § 41.37, Appellant presents an Appeal Brief in the above-captioned application.

This is an appeal to the Board of Patent Appeals and Interferences from the Examiner's final rejection of claims 1-18 in the Final Office Action dated April 8, 2008. The appealed claims are set forth in the attached Claims Appendix.

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1. Real Party in Interest

This application is assigned to NAMIC/VA, Inc., the real party in interest.

2. Related Appeals and Interferences

An Appeal Brief was filed in connection with the present application on June 4, 2007. The application was subsequently reopened for examination and a Non-Final Office Action containing a new grounds of rejection was mailed on September 24, 2007.

3. Status of the Claims

Claims 1 - 18 have been rejected in the Final Office Action, and are the subject of the present appeal.

4. Status of Amendments

All amendments submitted by the Appellant have been entered.

5. Summary of Claimed Subject Matter

Independent claim 1 recites an access port 100 comprising a housing with a first opening 202 therein and a septum 106 containing an operative surface 112 mounted within said housing sealing the first opening 202 and self-sealing after penetration by a needle. (*See* Specification, p. 6, li. 22 – p. 7, li. 6; Figs. 1, 2). Claim 1 also recites that the septum 106 is secured to the housing via an attachment portion 114, wherein the attachment portion 114 includes an annular surface 210 extending radially beyond a periphery of the operative surface of the membrane 112. (*Id.*, p. 7, ll. 6-24; Fig. 2). The annular surface 210 is coupled with the operative surface of the membrane 112 by a chamfer portion 208, the chamfer portion 208 being subject to a force

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substantially perpendicular to the annular surface 210. (*Id.*, p. 7, ll. 10 - 18; Figs. 2, 3). Claim 1 also recites that the chamfered portion 208 of the access port 100 redirects a portion of the force to compress the operative surface of the membrane 112 in a direction parallel to the annular surface 210. (*Id.*, p. 7, li. 29 – p. 8, li. 4; Fig. 3).

Independent claim 12 recites a septum 106 for an access port 100 comprising an attachment portion 114 including an annular surface 210 adapted to abut a septum seat 204 of the access port 100. (*Id.*, p. 7, ll. 20-27; Fig. 2). Furthermore, claim 12 recites a self sealing operative surface 112 located on the septum 106 permits penetration by a needle wherein a periphery of the operative surface 112 is located radially within a periphery of the annular surface 210 of the septum 106. (*Id.*, p. 7, ll. 5 - 12). Claim 12 also recites a chamfered portion 208 of the septum 106 which provides a transition between the attachment portion 114 and the operative surface 112. This chamfered portion 208 redirects a portion of a force applied thereon to compress the operative surface 112. (*Id.*, p. 7, ll. 10-18; Fig. 3).

6. Grounds of Rejection to be Reviewed on Appeal

- I. Whether Claims 1- 18 are Unpatentable Under 35 U.S.C. § 102 (b) as Anticipated by Johnson (U.S. Patent No. 5,989,216).
- II. Whether Claims 1 and 12 are Unpatentable Under 35 U.S.C. § 102 (b) as Anticipated by Wiita (U.S. Patent No. 4,772,270) or Bark (U.S. Patent No. 4,904,241).

7. Argument

I. The Rejection of Claims 1- 18 Under 35 U.S.C. § 102 (b) as Anticipated by Johnson Should be Reversed

A. The Examiner's Rejection

In the Final Office Action, the Examiner has rejected claims 1 - 18 under 35 U.S.C.

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102(b) as unpatentable over Johnson. (See 4/8/2008 Office Action, pp. 2 - 5).

Claim 1 recites an access port comprising a septum including an operative surface covering an opening of a housing and an attachment portion for securing the septum to the housing and further including "an annular surface extending radially beyond a periphery of the operative surface and separated from the operative surface in a direction substantially perpendicular to the annular surface." Claim 1 further states that the annular surface is coupled to the operative surface by a chamfer which, when the septum is mounted within the housing, is subject to a force oriented substantially perpendicularly with respect to the annular surface, the chamfered portion redirecting a portion of the force to compress the operative surface in a direction substantially parallel to the annular surface."

B. The Cited Reference Does Not Disclose a Chamfer as Recited in Claims 1 and 12

Johnson fails to teach or suggest an "annular surface being coupled to the operative surface by a chamfer which, when the septum is mounted within the housing, is subject to a force oriented substantially perpendicularly with respect to the annular surface, the chamfered portion redirecting a portion of the force to compress the operative surface in a direction substantially parallel to the annular surface," as recited in claim 1.

Initially, it is noted that Johnson fails to define the elements referenced in support of the rejection and, furthermore, that the conclusions drawn by the Examiner regarding the elements of the Johnson device are incorrect and speculative at best. Specifically, the Examiner has indicated that a curved portion in Johnson "with a substantially constant radius of curvature" is analogous to the "chamfered portion *providing a transition between the attachment portion and the operative surface*," as recited in claim 1. (See 4/8/08 Office Action, pp. 2 - 4). However, its is

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respectfully submitted that the rounded portion of the Johnson device referred to by the Examiner projects out of the housing 120 and is therefore incapable of being "subject to a force oriented substantially perpendicularly with respect to the annular surface," as claimed or of "redirecting a portion of the force to compress the operative surface in a direction substantially parallel to the annular surface," as recited in claim 1. The Examiner has further affirmed the above by indicating that the rounded portion of the septum 122 is "not fully completely enclosed by the housing." (See 4/8/08 Office Action, p. 2). However, it is further submitted that no part of the rounded portion of the septum 122 is received within the housing. It is thus unclear what the Examiner has relied in support of his interpretation otherwise, especially in light of the fact that Johnson explicitly focuses on the employment of "a septum which is non-compressively held in a housing." (Id., col. 4, lines 49 - 65). It is respectfully submitted that only the straightened side walls of the septum 122, which the Examiner analogizes to the "attachment portion" of claim 1 are received within the housing 120. (See Johnson, col. 5, lines 57 - 60; Figs. 10, 11). By virtue of its positioning external to the housing 120, it is submitted that the so-called chamfer of Johnson is incapable of receiving a compressive force and does not meet the limitation of being "subject to a force oriented substantially perpendicularly with respect to the annular surface," as recited in claim 1.

Appellants therefore respectfully submit that Johnson fails to teach or suggest the limitation of an "annular surface being coupled to the operative surface by a chamfer which, when the septum is mounted within the housing, is subject to a force oriented substantially perpendicularly with respect to the annular surface, the chamfered portion redirecting a portion of the force to compress the operative surface in a direction substantially parallel to the annular surface," as recited in claim 1. It is therefore submitted that claim 1 and its dependent claims 2 - 11 are allowable over Johnson for at least this reason.

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Additionally, as indicated above, Johnson is directed only to non-compressively held septa. (*Id.*, col. 4, lines 49 - 65). It is therefore further noted that Johnson fails to teach a septum showing *any* specific behavior when subject to a compressive force at all and specifically teaches away from any modification of its device which would compress the septa. Specifically, Johnson discloses that the septum 122 is held in place in the housing 120 by being shoehorned in, as shown in Fig. 8, or being dropped in, as shown in Fig. 9, wherein the septum is bonded to the housing 120 with an adhesion promoter and not through any compressive forces on the septum. (*Id.*, col. 7, ll. 10 - 20; Figs. 8 - 11). Johnson goes on to state that neither the housing 120 nor any other components exert forces across the entire vertical dimension of the septum. (*Id.*). It is therefore submitted that Johnson fails to teach or suggest "a chamfer which, when the septum is mounted within the housing, is subject to a force oriented substantially perpendicularly with respect to the annular surface, *the chamfered portion redirecting a portion of the force to compress the operative surface in a direction substantially parallel to the annular surface*," as recited in claim 1 and actually teaches away from such an embodiment.

Still further, it is respectfully submitted Johnson does not disclose or define a chamfer portion at all and that the Examiner's rejection is improperly based on speculation and a hindsight reconstruction of the invention. Specifically, Johnson neither shows nor suggests "a chamfer which, when the septum is mounted within the housing, *is subject to a force oriented substantially perpendicularly with respect to the annular surface*, the chamfered portion redirecting a portion of the force to compress the operative surface in a direction substantially parallel to the annular surface", as recited in claim 1. It is submitted that claim 1 and its dependent claims 2 - 11 are therefore allowable over Johnson for at least these additional reasons.

Claim 12 recites substantially similar limitations as claim 1, including a septum for an

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access port, comprising: "an attachment portion adapted to abut a septum seat of the access port, the attachment portion including an annular surface; an operative surface adapted to permit penetration by a needle and resealing itself after removal of the needle, a periphery of the operative surface being radially within a periphery of the annular surface; and a chamfered portion providing a transition between the attachment portion and the operative surface, the chamfered portion re-directing a component of a force applied to the chamfered portion to compress the operative surface." It is therefore respectfully submitted that claim 12 and its dependent claims 13-18 are allowable over Johnson for the same reasons noted above with regard to claim 1.

II. The Rejection of Claims 1 and 12 Under 35 U.S.C. § 102 (b) as Anticipated by Wiita or Bark Should be Reversed

A. The Examiner's Rejection

In the Final Office Action, the Examiner rejects claims 1 and 12 under 35 U.S.C. 102(b) as being anticipated by Wiita or Bark alone. (*See* 4/8/2008 Office Action, p. 5).

B. The Cited Reference Does Not Disclose a Chamfer Portion, as Recited in Claims 1 and 12

It is submitted that Wiita does not teach or suggest a chamfered portion "providing a transition between the attachment portion and the operative surface," as recited in claim 1. The septum of Wiita includes what appears to be a substantially planar annular surface extending radially outward from the central operative portion. The Examiner has previously contended that the shoulder 24 of the Wiita device is comparable to the recited chamfer portion. However, it is noted that the shoulder 24 of Wiita is designated as an inner wall of the port 10 and does not

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constitute a chamfer formed *on the septum*. (*See* Wiita, col. 4, li. 68 – col. 5, li. 4; Fig. 2). If the Examiner intended to refer to the portion of the septum 70 abutting the shoulder 24, this reference would also be insufficient as this portion is designated as the annular ring 72, which the Examiner has compared to the "attachment portion" of claim 1. (*See* 9/24/07 Office Action, p. 4). That is, the same element can not serve as the attachment portion and as a separate element (the chamfered portion) "providing a transition between the attachment portion and the operative surface," as recited in claim 1.

Furthermore, it is respectfully submitted that the septum of Wiita includes no portion which, when mounted within a housing, "is subject to a force oriented substantially perpendicularly with respect to the annular surface, the chamfered portion redirecting a portion of the force to compress the operative surface in a direction substantially parallel to the annular surface", as recited in claim 1. Nothing in Wiita describes such a surface nor is any surface of the Wiita septum capable of redirecting force in this manner. This portion of the septum is not capable of receiving a "force oriented substantially perpendicularly with respect to the annular surface" and "redirecting a portion of the force to compress the operative surface in a direction substantially parallel to the annular surface," as recited in claim 1. Rather, this annular portion receives only forces parallel to the annular surface. Accordingly, it is submitted that Wiita fails to teach or suggest a chamfer portion "which, when the septum is mounted within the housing, is subject to a force oriented substantially perpendicularly with respect to the annular surface, the chamfered portion redirecting a portion of the force to compress the operative surface in a direction substantially parallel to the annular surface," as recited in claim 1 or "a chamfered portion providing a transition between the attachment portion and the operative surface, the chamfered portion re-directing a component of a force applied to the chamfered portion to compress the operative surface," as recited in claim 12. It is respectfully submitted that claims 1

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and 12 are therefore allowable over Wiita.

Bark purports to show a septum 10 comprising a needle penetrable seal member 34 having a reduced peripheral section 36 disposed on an inclined support surface 18 of the needle stop member 12. (See Bark, col. 3, ll. 56 - 58; col. 4, ll. 12 - 22; Fig. 2). The Examiner contends that the chamfer portion of the Bark device is defined by a portion lying near 36 and that the attachment portion is defined by a portion near support surface 18. (See 9/24/07 Office Action, p. 4). Initially, it is noted that the portion lying near 36 comprises a peripheral edge of the septum 10, wherein the reduced peripheral section 36 is in direct contact with the support surface 18. Accordingly, it is respectfully submitted that Bark fails to show a chamfer portion near reduced peripheral section 36 and an attachment portion lying near support surface 18 as the support surface 18 comprises the portion of the Bark housing that houses the reduced peripheral section 36 and the area lying near the reduced peripheral section 36 and the support surface 18 may not be properly designated as two separate components. In any case, these elements are all on a continuous inner surface of the septum and do not provide "a transition between the attachment portion and the operative surface, the chamfered portion re-directing a component of a force applied to the chamfered portion to compress the operative surface," as recited in claim 1. That is, claim 1 recites "an annular surface extending radially beyond a periphery of the operative surface and separated from the operative surface in a direction substantially perpendicular to the annular surface." The surface 18 cannot form both the annular surface and the operative surface and it is unclear how the surface 18 could provide a transition from the peripheral section 36 and the surface 34 -- the surface 18 simply extends between opposite ends of the section 36 and never contacts the surface 34.

Furthermore, Bark never discusses or suggests a chamfer which, when subject to a force oriented substantially perpendicularly with respect to an annular surface, redirects "a portion of

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the force to compress the operative surface in a direction substantially parallel to the annular surface," as recited in claim 1 or "a chamfered portion providing a transition between the attachment portion and the operative surface, the chamfered portion re-directing a component of a force applied to the chamfered portion to compress the operative surface," as recited in claim 12. Nor is any surface or structure of the septum of Bark suitable for a redirection of force as claimed. Accordingly, it is submitted that claims 1 and 12 are allowable over Bark.

8. Conclusion

For the reasons set forth above, Appellant respectfully requests that the Board reverse the final rejections of the claims by the Examiner under 35 U.S.C. § 102(b).

Respectfully submitted,

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CLAIMS APPENDIX

1. (Previously Presented) An access port comprising:

a housing with a first opening formed therein; and

a septum mounted within the housing sealing the first opening, the septum including an operative surface covering the first opening and self-sealing after penetration by a needle and an attachment portion for securing the septum to the housing, the attachment portion including an annular surface extending radially beyond a periphery of the operative surface and separated from the operative surface in a direction substantially perpendicular to the annular surface, the annular surface being coupled to the operative surface by a chamfer which, when the septum is mounted within the housing, is subject to a force oriented substantially perpendicularly with respect to the annular surface, the chamfered portion redirecting a portion of the force to compress the operative surface in a direction substantially parallel to the annular surface.

- 2. (Original) The access port according to claim 1, wherein the housing includes a second opening for connection to a catheter.
- 3. (Original) The access port according to claim 1, wherein a base of the housing forms a septum seat and a cover of the housing secures the septum on the seat so that the attachment portion is compressed therebetween.
- 4. (Previously Presented) The access port according to claim 1, wherein the chamfer comprises at least one surface angled relative to the operative surface and the annular

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surface.

5. (Original) The access port according to claim 4, wherein the at least one angled surface forms a 45 degree angle to the operative surface.

- 6. (Original) The access port according to claim 1, wherein the chamfer comprises a stepped surface extending away from the operative surface.
- 7. (Original) The access port according to claim 1, wherein the chamfer comprises a curved fillet extending away from the operative surface.
- 8. (Original) The access port according to claim 7, wherein the curved fillet has a substantially constant radius of curvature.
- 9. (Previously Presented) The access port according to claim 1, wherein the annular surface abuts a septum seat of the housing.
- 10. (Original) The access port according to claim 1, wherein the operative surface comprises a substantially planar membrane overlying the first opening.
- 11. (Original) The access port according to claim 1, wherein the operative surface comprises a membrane which, when unconstrained has a dimension greater than a corresponding dimension of the first opening so that, when placed within the first opening the operative surface is compressed thereby.

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12. (Previously Presented) A septum for an access port, comprising:

an attachment portion adapted to abut a septum seat of the access port, the attachment portion including an annular surface;

an operative surface adapted to permit penetration by a needle and resealing itself after removal of the needle, a periphery of the operative surface being radially within a periphery of the annular surface; and

a chamfered portion providing a transition between the attachment portion and the operative surface, the chamfered portion re-directing a component of a force applied to the chamfered portion to compress the operative surface.

- 13. (Original) The septum according to claim 12, wherein the operative surface is sized to substantially overlie an opening of the access port.
- 14. (Original) The septum according to claim 12, wherein the chamfer portion is adapted to apply to the operative surface a radially compressive component of a force applied substantially perpendicularly thereto by assembly of the access port.
- 15. (Original) The septum according to claim 12, wherein the chamfered portion comprises a fillet joining the operative surface to the attachment portion.
- 16. (Original) The septum according to claim 12, wherein the chamfered portion comprises an angled surface joining the operative surface to the attachment portion.

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17. (Original) The septum according to claim 12, wherein the chamfered portion comprises a stepped surface joining the operative surface to the attachment portion.

(Original) The septum according to claim 12, wherein the operative surface is formed of a 18. flexible polymeric material.

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EVIDENCE APPENDIX

No evidence has been submitted herewith or is relied upon in the present appeal.

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RELATED PROCEEDINGS APPENDIX

There are no related proceedings and/or decisions which relate to the present appeal.